REPOSITORY/ REGISTRY USE/RELEASE VERIFICATION FORM

Introduction/Instructions

Registries (data banks) and repositories (tissue banks, usually with databases associated) all involve the collection and storage of information and/or biological specimens that researchers can utilize to address important scientific questions. Investigators wishing to collect private information and/or specimens to be stored and maintained in any of these ways must meet certain conditions outlined in the IRB approved protocol.

As part of the approved IRB protocol, potential future uses are outlined in the consent form as a way of advising donors how their specimens and/or health information may be used for research. It is the study team's responsibility to ensure that materials are used in a manner that respects the parameters of the consent provided by donors.

Each requested use/release should be considered carefully *by the repository/registry PI/Study Staff*, to ensure compliance with the IRB approved consent and application. The most important guidelines include:

- Requiring that the Registry/Repository PI ensure that any research conducted with the data/specimens adhere to the defined objectives;
- Requiring that data/specimens released be stripped of any direct and indirect identifiers prior to its release (HIPAA identifiers are appended at the end of this form); AND
- Requiring that direct access to the collected data/specimens and linking list be restricted to identified individuals on the approved repository/registry IRB application.

Use of this form* *(or an equivalent form developed as part of an approved Registry/Repository Management Plan)* *is required* *to document this review has occurred* *for each requested use/release of data and/or specimens. As long as a request for future research use meets the guidelines defined above and in the request form, use/sharing may occur without separate IRB approval from the requesting investigator. However, all uses/releases of deidentified data/specimens will be considered annually by the IRB at the time of the repository/registry continuing review, to confirm the approved management plan has been followed appropriately.

If the repository/registry PI/study staff is unsure whether a request for data/specimens meets the outlined objectives of the approved collection and/or the parameters of what was described in the approved consent form, please contact the IRB at 3-3783 for guidance BEFORE releasing data/specimens.

At each continuing review, the PI of the repository/registry will be required to upload copies of each use/release, and provide assurance that all were consistent with the approved protocol/consent.

REPOSITORY/ REGISTRY USE/RELEASE VERIFICATION FORM

Application Reference #:
(To be completed by the Repository/Registry Staff)

Request to Use Data and/or Specimens From:

Repository/Registry Name: _________________________

Repository/Registry IRB #: _________________________

Requesting Investigator's Name, Affiliation and Title:
NOTE: If requesting investigator is listed on the IRB approved repository/registry, s/he must provide assurance that s/he will not access the repository/registry personally in order to use/release data/specimens for the requested research.

Proposed Use/Analysis Study Title:

Condition/Disease to be Studied (e.g., diabetes, cancer, arthritis, etc.):

Purpose/Objectives of the Research (*1-2 paragraphs, in layman's language*)

What EXACTLY is being requested? (*include specific information about the need for data associated with each sample, if any, e.g., gender, age, date of birth, date of diagnosis, treatments received, etc.*)

INCLUDE A LIST OF ALL DATA POINTS AND/OR SPECIMENS BEING REQUESTED, E.G.:

DATA POINT/SPECIMEN TYPE	ANY SPECIAL INSTRUCTIONS

Requesting Investigator Assurances:

1. ***Any research conducted with the data/specimens released to me will adhere to the defined objectives of the approved repository/registry.***
2. ***If I am also an investigator or staff member listed on the repository/registry application, I will not access the repository/registry myself in order to pull the requested data/specimens for this research and will not, under any circumstances, have access to a key linking data/specimens to direct identifiers.***
3. ***I will not access any other sources (e.g., medical records) in order to obtain more data for this research without prior IRB approval to do so.***
4. ***I will not transfer any data/specimens to a third party without prior IRB approval to do so.***

____ ____________________
Requesting Investigator Signature **Date**

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Application Reference #:
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Assessing Whether Separate CSMC IRB Approval is Required:

All of the following are to be completed by Repository/Registry Staff

NOTE: A "No" response to any item below, will require separate CSMC IRB review and approval before use/sharing can occur.

1. *Does the intended purpose/objectives of the proposed analysis fall within the objectives of the repository/registry (including the condition/disease being studied and the future uses described in the repository/registry consent form)?*

   Yes □ ***No*** □

2. *Are ALL of the specimens/data requested currently collected by the repository/registry?*

   Yes □ ***No*** □

   2a. If no*, will the repository/registry IRB application be amended to accommodate this request?*

   Yes □ ***No*** □

3. *Can the proposed use/release of data/specimens be accomplished without releasing ANY of the 18 HIPAA identifiers (see attached list)?[NOTE: Use/release of the tracking ID# ("code") and dates (birthdates or dates related to treatment) is allowed under the IRB approval of the repository/registry, as a limited data set.]*

   Yes □ ***No*** □

4. *Has the investigator signed the form to provide his/her required assurances?*

   Yes □ ***No*** □

If ANY "No" response(s) is given above, enter either:

- ***the separate CSMC IRB-Approved Protocol # ______________________________ OR***
- ***the repository/registry amendment # ______________________________________***

BEFORE using/releasing data/specimens.

REPOSITORY/ REGISTRY USE/RELEASE VERIFICATION FORM

Application Reference #:
(To be completed by the Repository/Registry Staff)

DATA/SPECIMEN USE/RELEASE TRACKING

Date:

Repository/Registry Accessed By:

(circle all that apply)
Data/Specimens Used/Released To:

Notes:

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In compliance with the Privacy Rule (45 CFR Part 160 and Subparts A and E of Part 164), and in accordance with DHHS guidance on Protecting Personal Health Information in Research, covered entities (such as CSMC) are allowed to de-identify data *by removing all 18 elements that could be used to identify the individual or the individual's relatives, employers, or household members*; these elements are enumerated in the Privacy Rule. The covered entity also must have no actual knowledge that the remaining information could be used alone or in combination with other information to identify the individual who is the subject of the information. Under this method, the identifiers that must be removed are the following:

1. Names
2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP Code, and their equivalent geographical codes, except for the initial three digits of a ZIP Code if, according to the current publicly available data from the Bureau of the Census:
    a. The geographic unit formed by combining all ZIP Codes with the same three initial digits contains more than 20,000 people.
    b. The initial three digits of a ZIP Code for all such geographic units containing 20,000 or fewer people are changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
4. Telephone numbers
5. Facsimile (FAX) numbers
6. Electronic mail (e-mail) addresses
7. Social security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web universal resource locators (URLs)
15. Internet protocol (IP) address numbers
16. Biometric identifiers, including fingerprints and voiceprints
17. Full-face photographic images and any comparable images
18. Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.